

REMARKS

By the foregoing amendments to the claims, claims 8-12 have been canceled, claim 18 has been amended and claims 21-25 have been added. Support for the newly added claims can be found throughout the application. For example, support for claims 21 and 24 can be found in paragraph [202] of the published version of the present Application, namely U.S. Patent Application Publication No. 2004/258740 A1. Support for claim 22 can be found in claim 19 and in paragraph [107], and support for claim 23 is described in paragraph [124].

Applicant notes that no disclaimer should be associated with the cancellation of previously withdrawn claims 8-12 and that Applicant reserves the right to pursue patentability of these claims in a continuation application.

Formal Matters

Applicant acknowledges that the Examiner has made the Restriction Requirement final. However, Applicant notes that this acknowledgment does not constitute a disclaimer of the non-elected subject matter and reserves the right to prosecute such non-elected subject matter in one or more divisional applications.

Applicant thanks the Examiner for consideration of the information submitted in the Information Disclosure Statement filed July 9, 2004 by returning a signed and initialed copy of the Form PTO-1449.

Claim Rejections – 35 U.S.C. § 102

The Office Action rejects claim 18 under 35 U.S.C § 102 (b) as being anticipated by each of the following list of documents:

- a) U.S. Patent No. 5,527,832 to Chi et al.;
- b) U.S. Patent No. 5,780,047 to Kamiya et al.;
- c) U.S. Patent No. 5,976,566 to Samour et al.;
- d) U.S. Patent No. 6,083,996 to Büyüktimkin et al.; and
- e) U.S. Patent Application Publication No. 2001/0036489 A1 to Youssefeyeh.

The Office Action asserts that each of the above-listed documents by itself anticipates claim 18.

Applicant respectfully submits that the foregoing amendments render these rejections moot.

As the Examiner is well aware, for a anticipation rejection to be valid, each and every feature of the claim must be disclosed in the cited document. Applicant notes that with respect to the above documents a, b, c, d, and e, none of the documents either discloses “first, dissolving in a bath a pharmaceutical composition” and/or “second, immersing a body part . . . in the bath.” In the absence of any disclosure of these recitations in the cited documents, there cannot be a proper anticipation rejection.

Applicant notes that the documents b), '047, and e), '489, are the only two documents that discuss the application of a bath. However, Applicant respectfully submits that these documents also fail to anticipate the presently claimed method.

As for b) and by the foregoing amendment, Applicant respectfully submits that b) fails to disclose an effervescent agent.. Thus, b) fails to anticipate present claim 18. Withdrawal of this rejection is respectfully requested.

As for e), Applicant respectfully submits that this document lacks a composition for transdermal delivery as recited in present claim 18. As the Examiner is surely aware, safflower seeds, either whole or finely divided, are (i) not a pharmaceutical composition and (ii), even assuming, *arguendo*, that this were some sort of a pharmaceutical composition, there is no disclosure in e) as to any transdermal delivery of an active ingredient. Therefore, e) fails to present a proper anticipation rejection.

In view of the foregoing, Applicant respectfully requests withdrawal of all § 102 rejections

Claim Rejections – 35 U.S.C. § 103

The Office Action rejects claims 18 and 19 under 35 U.S.C § 103 (a) as being obvious over the combination of documents b), U.S. Patent No. 5,342,535 ("535"), e) and d) (above). The Action asserts that the combination of these documents renders claims 18 and 19 obvious.

Applicant respectfully traverses these rejections. Initially, Applicant respectfully submits that the Action fails to show a reason as to why one of ordinary skill in the art would combine document b) with any of the secondary references to cure the deficiency of document b).

The Examiner is respectfully reminded that “[a] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct., 1741.

Applying *KSR Int'l Co.* here, Applicant asks why should one of ordinary skill in the art combine document b), which does not contain an effervescent agent as recited in claim 18 with any of the secondary references that allegedly cure this deficiency, if there is no reason in document b) to prompt this combination. Assuming – *arguendo* - that such combination would be proper, one of ordinary skill would arrive at a patch that contains an effervescent formulation. Therefore, Applicant respectfully requests that the Examiner clarifies what combination of the cited documents renders which recitation of the presently claimed method obvious. Otherwise, even under *KSR Int'l Co. v. Teleflex Inc.*, in the absence of such explanation, there is no proper obviousness rejection and withdrawal of all of the above rejections under 35 U.S.C. § 103(a) is respectfully requested.

In addition to the foregoing, Applicant respectfully submits, that document b) teaches a method wherein a composition in form of a patch is preferably first administered to a patient before the patient takes a bath. Applicant notes that it would be counterintuitive to one of ordinary skill in the art to apply the teachings of b) and reverse the order of application by first dissolving the composition –here, the patch- in a bath prior to administering to a body part. Secondly, Applicant notes that a physiological effect would be minimized by diluting any dosage form in a bath before a body part comes in contact with the active ingredient. Therefore, one of ordinary skill would not be motivated to first dissolve any pharmaceutical composition in a bath because of the dilution of the active ingredient that would be counterintuitive to the original mode of administering the active ingredient.

As for '535, this document discloses an effervescent formulation. Even assuming that the above combination is proper, one of ordinary skill would not be motivated to dissolve a composition first in a bath and then immerse the body part in the bath. This deficiency is not cured by document d) as this document refers to "an aqueous pharmaceutical composition of semi-solid consistency" (document d), column 2, line 2) and thus, this document would at best be cumulative to document b). As for document e), Applicant respectfully submits that the combination of b) and e) would still not teach or suggest to one of ordinary skill in the art to first dissolve a pharmaceutical composition in a bath prior to immersing a body part therein. In fact, Applicant notes that the combination of b) and e) would suggest to the ordinary artisan, that a person may apply a pharmaceutical patch to a body part followed by taking a bath that contains safflower powder. Yet, this combination even if including document d) or '535 would still not arrive at the presently claimed invention.

Applicant submits that the Action fails to identify any reason that would have prompted a person of ordinary skill in the art to show how any document or combination of documents of the above rejections under 35 U.S.C. § 103(a) would suggest to or motivate one of ordinary skill to apply a method as claimed in claim 18. For example, Applicant respectfully requests why one of ordinary skill relying on '047 pertaining to a patch that is applied to a patient would be motivated to combine that document with '535, which in its majority describes effervescent formulations.

Even assuming, *arguendo*, that all the documents raised under the obviousness rejection would be combined, Applicant respectfully notes for the reasons explained above that the combination does not show a pharmaceutical composition for transdermal that is first dissolved in a bath prior to immersing a body part therein.

Moreover, besides the above described dilution of an active ingredient into a bath which would be counterintuitive to one of ordinary skill in the art to arrive at the present invention in view of the cited documents, another feature of the presently claimed method should be considered. Applicant notes that the sole dispersing and/or dissolution of an active ingredient such as ibuprofen in bath water does not result in the requisite absorption of the active ingredient through the skin to obtain the beneficial effect. Rather, an oil phase including a skin permeation enhancer layer has to present. This layer adsorbs evenly across the skin and enhances permeation of the active ingredient across the skin barrier.

During the bath, the active ingredient, here Ibuprofen, converts from a water soluble form, e.g. as a salt, into a lipophilic form, e.g. a non-salt form upon entering into the oil phase that spans the patient's skin. As absorption of the active ingredient into the oil phase increases, diffusion into the skin augments. Thus, the oily layer across the skin is essential to ensure desired permeation of the active ingredient. Furthermore, absorption into the skin even continues after the body or body part is removed from the bath because the oily layer across the skin still contains active ingredients that permeate the skin.

In view of the foregoing, Applicant respectfully submits that one of ordinary skill would not expect to arrive at the presently claimed invention when diluting a pharmaceutical composition in the absence of agents that ensure the dissolving of the active ingredient (here effervescent agents) or a skin permeation enhancer in amounts sufficient to build the permeation layer across the skin.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the rejections should be withdrawn. Favorable consideration with early allowance of all of the pending claims is most earnestly requested.

If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully Submitted,
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